

Margaret Brivanlou. As discussed and made of record below, the interview clarified the substance of the Office Action (*i.e.*, Restriction Requirement).

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-72 and 85-199, drawn to a method of preventing or treating an RSV infection, classified in class 435, subclass 5; and
- II. Claims 73-84, drawn to a pharmaceutical composition comprising SYNAGIS®, classified 424, subclass 130.1.

The Examiner contends that the inventions of Groups I and II are distinct from each other. Applicants hereby elect to prosecute the claims of Group I, claims 1-72 and 85-199, drawn to a method of preventing or treating an RSV infection, without prejudice to Applicants' right to pursue the non-elected subject matter in other applications.

Group I, claims 1-72 and 85-199, is further subject to a restriction which requires Applicants to elect one of the following antibodies: SYNAGIS®, AFFF, P12F2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4, or A8c7. The Examiner contends that further restriction is required for claim 179 and that Applicants must elect one of the following sequences: SEQ ID NO:1, 10, 17, 2, 18, 24, 37, 41, 45, 3, 11, 19, 26, 29, 4, 13, 21, 31, 39, 47, 53, 73, 5, 14, 22, 27, 32, 35, 43, 50, 54, 59, 61, 63, 66, 69, 72, 6 or 15.

In the interview discussion, Examiners Brown and Park stated that the requirement to elect a single antibody (*i.e.*, SYNAGIS®, AFFF, P12F2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4, or A8c7) upon election of Group I did not apply to all of the claims in Group I. Rather, the Examiners stated that the election of a single antibody upon election of Group I only applied to the particular dependent claims that recite the specific antibodies, *i.e.*, claims 18, 44, 72, 85-110, 139, and 179. The Examiners stated that the full breadth of the claims 1-17, 19-43, 45-71, 123-138, 140-148, 156-178, and 180-191 which generically recite an anti-RSV antibody rather than a specific anti-RSV antibody will be examined. Accordingly, Applicants are responding to this Restriction Requirement based upon the Examiners' interpretation. If further restriction is imposed on all of the claims, Applicants reserve the right to object.

Applicants respectfully traverse the restrictions requiring the election of a particular antibody and the election of a particular CDR amino acid sequence. Applicants respectfully assert that a single search would identify any relevant art pertaining to a method of preventing

or treating a respiratory syncytial virus (RSV) in a mammal comprising administering to said mammal a particular dosing regime of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, regardless of the particular amino acid sequence of the antibody or a CDR thereof. Thus, contrary to the Examiner's contention, Applicants assert that to search and examine the subject matter of the antibodies and CDR sequences together would not be a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, August 2001) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of M.P.E.P. § 803, SYNAGIS®, AFFF, P12F2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4, and A8c7 and SEQ ID NO:1, 10, 17, 2, 18, 24, 37, 41, 45, 3, 11, 19, 26, 29, 4, 13, 21, 31, 39, 47, 53, 73, 5, 14, 22, 27, 32, 35, 43, 50, 54, 59, 61, 63, 66, 69, 72, 6 and 15 should be searched and examined in the subject application.

At a minimum, the requirement to elect a particular antibody should be modified to a species election. Pursuant to M.P.E.P. § 806.04(d), claims 1-17, 19-43, 45-71, 123-138, 140-148, 156-178, and 180-191 are generic claims which generically recite antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens. Dependent claims 18, 44, 72, 85-110, 139, and 179 merely recite specific species of anti-RSV antibodies for use in the methods claimed. Under 37 C.F.R. § 1.146,

[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentability distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.

Thus, under the Rules of Practice, a species election, not further restriction is, at most, the appropriate action in this matter. Accordingly, Applicants respectfully request that the further Restriction Requirement Under 35 U.S.C. § 121 of Group I be withdrawn or modified such that SYNAGIS®, AFFF, P12F2, P12F4, P11d4, Ale9, A12a6, A13c4, A17d4, A4B4, and A8c7 and SEQ ID NO:1, 10, 17, 2, 18, 24, 37, 41, 45, 3, 11, 19, 26, 29, 4, 13, 21, 31, 39, 47,

53, 73, 5, 14, 22, 27, 32, 35, 43, 50, 54, 59, 61, 63, 66, 69, 72, 6 and 15 are examined in one application, or at a minimum, that the further Restriction of Group I be modified to be a species election.

In order to be fully responsive, however, Applicants hereby elect to prosecute SYNAGIS® and SEQ ID NO:3, with traverse, without prejudice to Applicants' right to pursue the non-elected subject matter in other applications.

Entry of the remarks made herein is respectfully requested. The Examiner is invited to contact the undersigned with any questions concerning the foregoing.

Respectfully submitted,

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Enclosure

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